

DOT/FAA/AM-02/10

Office of Aerospace Medicine
Washington, DC 20591

The Aviation Accident Experience of Civilian Airmen With Refractive Surgery

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June 2002

Final Report

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U.S. Department
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**Federal Aviation
Administration**

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Technical Report Documentation Page

1. Report No. DOT/FAA/AM-02/10		2. Government Accession No.		3. Recipient's Catalog No.	
4. Title and Subtitle The Aviation Accident Experience of Civilian Airmen With Refractive Surgery				5. Report Date June 2002	
				6. Performing Organization Code	
7. Author(s) Nakagawara, V.B., Montgomery, R.W., and Wood, K.J.				8. Performing Organization Report No.	
9. Performing Organization Name and Address FAA Civil Aerospace Medical Institute P.O. Box 25082 Oklahoma City, OK 73125				10. Work Unit No. (TRAIS)	
				11. Contract or Grant No.	
12. Sponsoring Agency name and Address Office of Aerospace Medicine Federal Aviation Administration 800 Independence Ave, S.W. Washington, DC 20591				13. Type of Report and Period Covered	
				14. Sponsoring Agency Code	
15. Supplemental Notes					
16. Abstract <p>Introduction: Civil airmen with refractive surgery may obtain any class of Federal Aviation Administration (FAA) medical certificate provided they meet the applicable vision standards, and an eye specialist verifies that healing is complete, visual acuity is stable, and no significant glare intolerance is present. However, concerns remain regarding the quality of the resulting refractive correction, long-term stability, side effects, and the potential surgical complications associated with refractive surgery. The purpose of this study was to determine whether an association existed between refractive surgery and aviation accidents. Methods: Records for active airman during the study period, 1994-96, were extracted from the FAA's Consolidated Airman Information System medical database. Airmen who carried pathology codes for refractive surgery (130) and general eye surgery (5179) were identified. These records were cross-referenced with the Accident/Incident Data System database to determine those airmen involved in aircraft accidents. Frequency totals and mean accident rates (accidents/100,000 flight hours) were calculated for each class of FAA medical certification. Analysis of Variance was performed to compare the mean accident rates of non-refractive and refractive surgery airmen. Results: The total accident rate was higher for airmen with refractive surgery (3.86/100,000 flight hours) when compared with those without refractive procedures (2.62/100,000 flight hours). Accident rates for airmen with refractive surgery were also higher in all three classes of medical certification; however, analysis found that these differences were not statistically significant ($p > 0.05$) for any class of medical certification or the total airman population. In addition, our review found no aviation accident in which refractive surgery was identified as a causal factor. Conclusions: Although accident rates of refractive surgery airmen were higher, no direct association was identified between refractive surgery and aviation accidents. Monitoring will be ongoing to ensure that airmen with newer laser refractive procedures perform safely in the aviation environment.</p>					
17. Key Words Refractive Surgery, Aviation Vision, Accident Risk			18. Distribution Statement Document is available to the public through the National Technical Information Service; Springfield, Virginia 22161		
19. Security Classif. (of this report) Unclassified		20. Security Classif. (of this page) Unclassified		21. No. of Pages 16	
				22. Price	

THE AVIATION ACCIDENT EXPERIENCE OF CIVILIAN AIRMEN WITH REFRACTIVE SURGERY

INTRODUCTION

Optimum vision is essential for pilots to ensure safe flight operations. The pilot must see well at distance to detect and identify airborne traffic, as well as hazards that may be on runways and taxiways. Good intermediate and near vision is also essential since cockpit instruments and aviation materials such as flight manifests, charts, and maps must be clearly visible to properly execute flight procedures in varying ambient light conditions.

Refractive error is an optical defect that prevents light rays entering the eye to be focused as a single, clear image on the retina. Blurred vision from refractive error can interfere with a pilot's ability to efficiently perform operational tasks and can compromise aviation safety. Common refractive conditions (see Figure 1) that are correctable with ophthalmic devices (eyeglasses, contact lenses) include myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (irregular corneal curvature). Approximately 55% of the U.S. population rely on corrective lenses to achieve a quality of vision satisfactory for their daily needs (1).

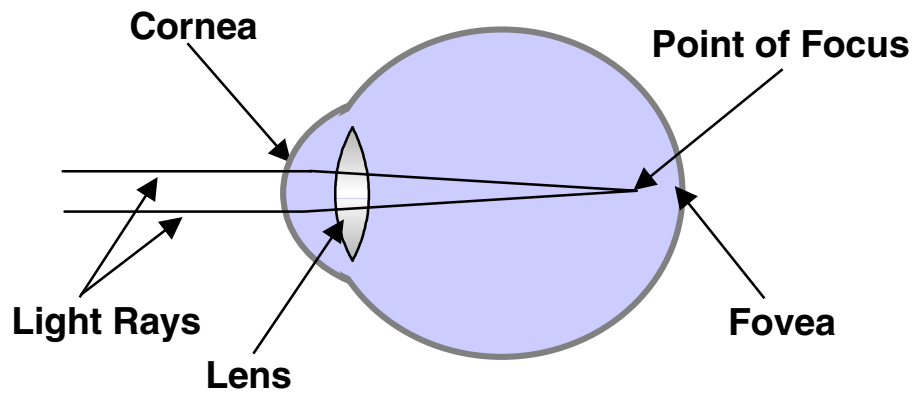
Civil airmen with refractive surgical procedures have been allowed to obtain Federal Aviation Administration (FAA) medical certificates since the early 1980s. The majority of these airmen had a procedure known as radial keratotomy (RK) performed to correct their defective distant vision. In 1995, the Food and Drug Administration (FDA) approved the use of the excimer laser to perform refractive surgery (2). Laser procedures, such as photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK), are being performed on a rapidly growing number of people, including civilian pilots (3). Presently, applicants with refractive surgical procedures may obtain an airman medical certificate without a waiver if they meet the visual acuity standards for the class of medical certificate applied, and an eyecare specialist verifies that their vision is stable, healing is complete, and no glare intolerance is present (4).

RK, PRK, and LASIK procedures are similar only in that the goal is to improve uncorrected visual acuity by permanently altering the curvature of the eye's outer surface or cornea. RK requires a surgeon to make a series of spoke-like incisions around the periphery of the

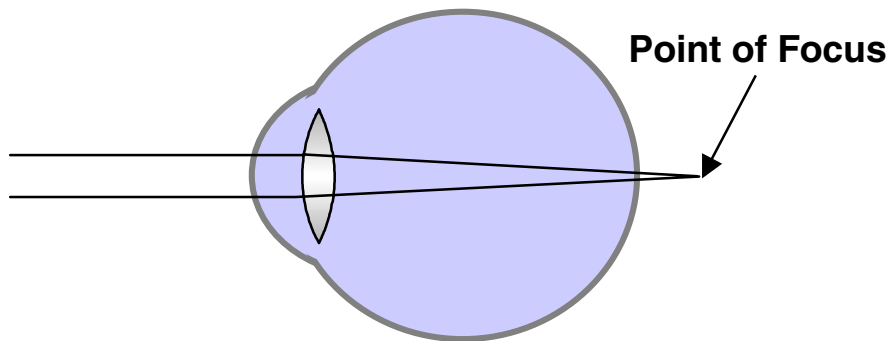
cornea that, once healed, flattens the cornea and reduces myopia. PRK reshapes the cornea through a process called photoablation, which utilizes the excimer laser to vaporize the cornea's outer tissue. LASIK uses a specially designed surgical scalpel (microkeratome) to slice a thin horizontal flap from the top of the cornea leaving it connected by a small hinge of tissue. The flap is folded aside, and the excimer laser is used to remove tissue from the corneal stroma. The corneal flap is then returned to its original position (see Figure 2).

Approximately 1.3 million laser refractive surgical procedures were performed in the United States in the year 2000 (5) and a 35 to 40% growth rate is expected over the next five years (6). Success rates of 90% or better have been reported for patients with low-to-moderate myopia who have had laser refractive procedures (7,8,9). However, the criteria for success used in many of these studies permit uncorrected visual acuity (VA) as low as 20/40 (10). While a VA in this range may be adequate for the general population, pilots, who must safely perform a wide variety of vision-related flight operations under visually demanding environmental conditions, may find these results unacceptable (11). Aviation concerns remain regarding the quality of the resulting vision correction (12), side effects in the aviation environment (13,14,15), and the potential for surgical complications (16,17).

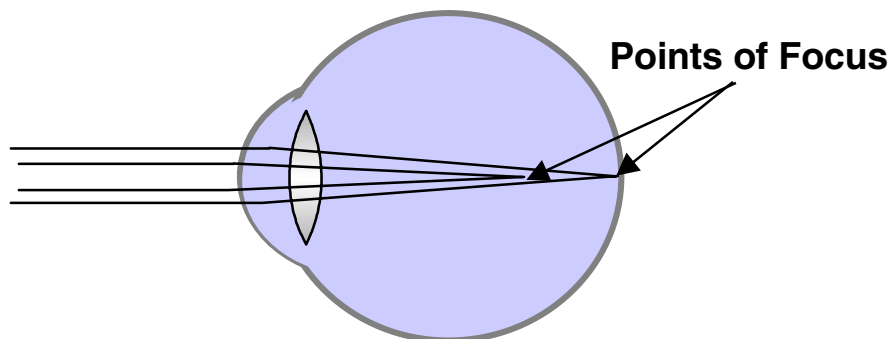
The aircraft accident experience of civilian pilots with refractive surgical procedures has not been previously examined or reported. Studies by Dille and Booze, conducted from 1976 to 1981, examined the relationship between aviation accidents and static visual conditions (18,19,20). Two of these studies found statistically significant associations between certain visual conditions and aircraft accidents (19,20). At that time, refractive surgery was not commonly used by aviators and was not one of the conditions studied. The recent growth in popularity of laser refractive surgery prompted a review of the aviation accident experience of airmen with refractive surgery (3). A retrospective, cross-sectional cohort study was performed to determine whether accident rates of airmen with refractive surgery differed significantly from those of airmen without refractive procedures during the study period (1994-96).



Myopia (nearsightedness)



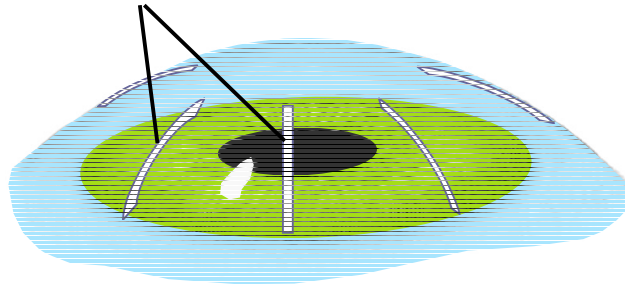
Hyperopia (farsightedness)



Astigmatism (irregular corneal curvature)

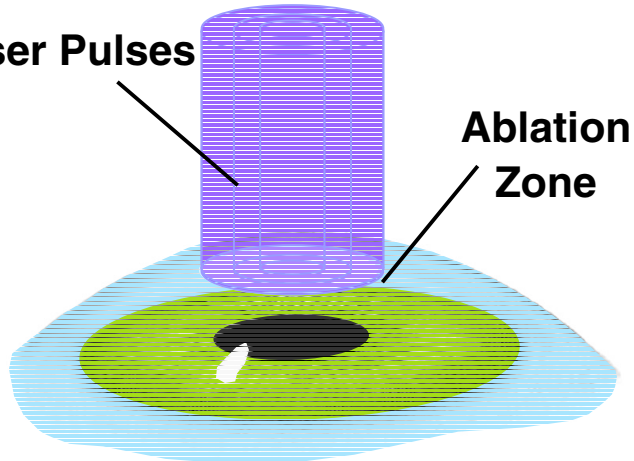
Figure 1: The three most common types of refractive conditions, myopia, hyperopia, and astigmatism.

Radial Incisions

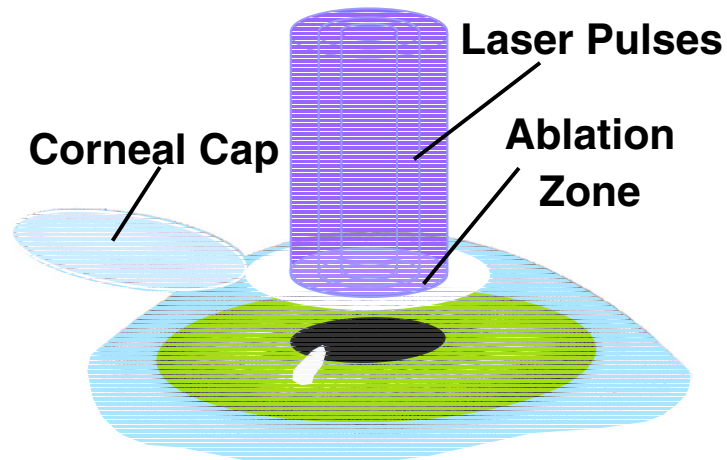


Radial Keratotomy

Laser Pulses



Photorefractive Keratectomy



Laser-Assisted in situ Keratomileusis

Figure 2: The most common refractive surgical procedures are Radial Keratotomy (RK), Photorefractive Keratectomy (PRK), and Laser-Assisted in situ Keratomileusis (LASIK).

METHODS

1. A query of the FAA's Comprehensive Airman Information System (CAIS) for all airmen who applied for airman medical certificates from 12/01/1992 to 12/31/1996 resulted in a database of 2,076,260 records. This database contained duplicate records for airmen that had multiple certification exams during a single year, incomplete airmen records, and records for airmen that were pending or denied during the study period (12/31/1994 to 12/31/1996). During this period, airmen were issued a medical certificate to perform the duties required of one of the three classes of certification, provided they met the medical standards for the applied class. The three classes of certification were valid under the following conditions:

a) A first-class certificate was valid for the month in which it was issued plus 6 months for activities requiring a first-class medical certificate, 12 months for activities requiring a second-class medical certificate, and 24 months for activities requiring a third-class medical certificate (4).

b) A second-class certificate was valid for the month in which it was issued plus 12 months for activities requiring a second-class medical certificate, and 24 months for activities requiring a third-class medical certificate (4).

c) A third-class certificate was valid for the month in which it was issued plus 24 months for activities requiring a third-class medical certificate (4). (Note: As of September 16, 1996, third-class medical certificates for airmen < 40 years of age are valid for the month in which it was issued plus 36 months. For third-class applicants \geq 40 years of age, the duration of the medical certificate is as in the original standard.)

2. The airmen records collected from the CAIS database were processed using a series of queries designed to eliminate all but the last medical record for airmen who were active at the end of each year of the study. This procedure eliminated 396,741 records, leaving 1,679,519 active airman records for the study period.

3. Airman records with medical certificates dated from 12/01/1992 to 12/31/1994 were extracted from this data and saved as the 1994 Active Airman Population database. A similar process was followed to create databases for years 1995 and 1996. This process involved changing the exam dates in the queries appropriately to extract the active airman records for individual years in the study period.

4. To construct the active airman database for airmen with refractive surgery, each of the three Active Airman Population databases was queried for the FAA-specific pathology codes 130 (radial keratotomy) and 5179 (general eye pathology with surgical prefix). Medical records of airmen with pathology code 5179 were reviewed to identify those airmen who had refractive surgery. (Note: The 5179 code is assigned to applicants with various eye surgeries, including refractive surgery.) The airmen with pathology code 5179 identified as having refractive surgery and those with pathology code 130 were combined into Refractive Surgery Population databases for each of the study years. There were a total of 7,753 records for active airmen with refractive surgery contained in these databases.

5. The records from 6,290 aviation accidents that occurred during the study years 1994-1996 were extracted from the Accident/Incident Data Systems (AIDS), which is maintained by the FAA's Aviation Standards National Field Office, Operations Systems Branch (AVN-124). This information included pilot identifiers (i.e., pilot name, certificate number, and date of birth). Records for 810 accidents were unusable, due to the lack of any pilot identifiers, resulting in a total of 5,480 accident records.

6. The 5,480 accident records were cross-referenced with the 1,679,519 airmen medical records of the three Active Airman Population databases. This allowed the addition of information not included in the AIDS database to the records of airmen involved in accidents, such as self-reported recent flight hours, class of medical certification, and pathology codes. A total of 1,283 accident records could not be matched, due to missing pilot certification numbers in the CAIS system. To further identify accident records, cross-referencing was performed using the pilot's name, social security number, and date of birth, resulting in a total accident database containing 4,197 records for the study period.

7. Once cross-referencing and categorization were completed, personal identifiers were stripped from the records, and study numbers were assigned to maintain confidentiality. The remaining data included class of medical certificate, age, and exposure (flight hours for the last six months). Annual exposure hours were estimated by doubling each airman's self-reported flight hours for the last six months.

8. From the information collected in these databases, accident frequencies and accident rates (accidents/100,000 hours) were calculated for the three classes (first-, second-, and third-class) of medical certification issued for both airmen with refractive surgery and without refractive surgery by year and for the study period.

$$\text{Accident Rate} = \frac{\text{Accident Frequency for Class and Group} \times 100,000 \text{ Flight Hours}}{\text{Annualized Exposure Hours for Class and Group}}$$

9. Frequency counts reported in this study include all available airman records. However, to avoid skewing the accident rates, frequency counts for airmen who had no self-reported hours for the last six months were deleted prior to calculating the accident rates. This action eliminated 1,742 (22%) of refractive surgery records and 396,667 (24%) of non-refractive surgery records. From the perspective of accident numbers, this action eliminated 395 (9%) of the accident and 398,014 (24%) of the non-accident records.

RESULTS

The total airman population by class for the study period (1994-96) is presented in Figure 3. The fewest number of aviators were in first-class (n=423,556), followed by second-class (n=434,192), and then third-class (n=815,771) airman populations. Figure 4 presents the refractive surgery population by class for the study period. As in the total airman population, the total refractive surgery population had the fewest number of aviators in first-class (n=1,507), followed by second-class (n=2,213), and then third-class (n=4,033) airman populations.

Accident frequencies for the non-refractive and refractive surgery airman populations are presented in Figures 5 and 6, respectively. First-class airmen in both the non-refractive surgery (n=815) and refractive surgery (n=6) airman populations had the fewest number of accidents. In the non-refractive surgery population, second-class airmen had more accidents (n=1,712) than third-class airmen (n=1,639) (see Figure 5). In the refractive surgery airman population, third-class airmen had more accidents (n=13) than second-class airmen (n=12) (see Figure 6).

Figure 7 presents the accident rates for the non-refractive surgery and refractive surgery airman populations. The vertical bars are indicative of the 5 to 95% confidence interval for each group. Third-class airmen exhibited the highest accident rates while first-class certificate holders had the lowest aviation accident experience. Refractive surgery airmen exhibited higher accident rates than their non-refractive surgery cohorts overall and for each class of medical certification. The variability was greater for accident rates of refractive surgery airmen, as indicated by the longer length of the vertical error bars, compared with those of the non-refractive surgery airmen.

The results of single-factor Analysis of Variance (ANOVA) are presented in Table 1. Although higher, the mean accident rates for airmen with refractive surgery were not significantly different ($p > 0.05$) compared to those airmen without refractive surgery. The p-values for the total, first-class, second-class, and third-class populations equal 0.279, 0.259, 0.612, and 0.282, respectively (see Table 1).

DISCUSSION

Pilots with third-class medical certificates have the highest aviation accident rates, while first-class certificate holders experienced the fewest number of accidents, despite their considerably higher exposure (i.e., recent flight hours). Mitigating factors for this difference between the classes of medical certification may include the different types of aircraft flown and the flight operations performed by these airmen. First-class certificate holders are primarily air transport pilots who fly large, sophisticated aircraft. The majority of second-class certificate holders are commercial pilots who may fly air cargo, corporate, agricultural, or small commuter aircraft. Third-class certificate holders are primarily private pilots who fly for personal business or pleasure in light, privately owned aircraft. Private pilots are required to have less frequent medical certification examinations, and their medical standards are less stringent than first- or second-class medical certificate holders (4.). These pilots often do not have the level of training and flight experience as their air transport or commercial counterparts. In addition, pilots with third-class medical certificates tend to be older (21), their aircraft may not be as carefully maintained, they usually fly without a co-pilot, have fewer cockpit resources to assist them in flight, and they are often not instrument rated. Finally, private pilots normally fly at lower altitudes where exposure to adverse weather conditions is greater, and recovery time in an emergency situation is shorter. Commercial pilots face similar limitations when compared to air transport pilots, although the differences are typically less substantial.

The accident rates for airmen with refractive surgery were higher than those of non-refractive surgery airmen within each class of medical certification and as a total group. Although their accident rates were higher, it is important to note that statistical analysis found that no significant ($p > 0.05$) association existed

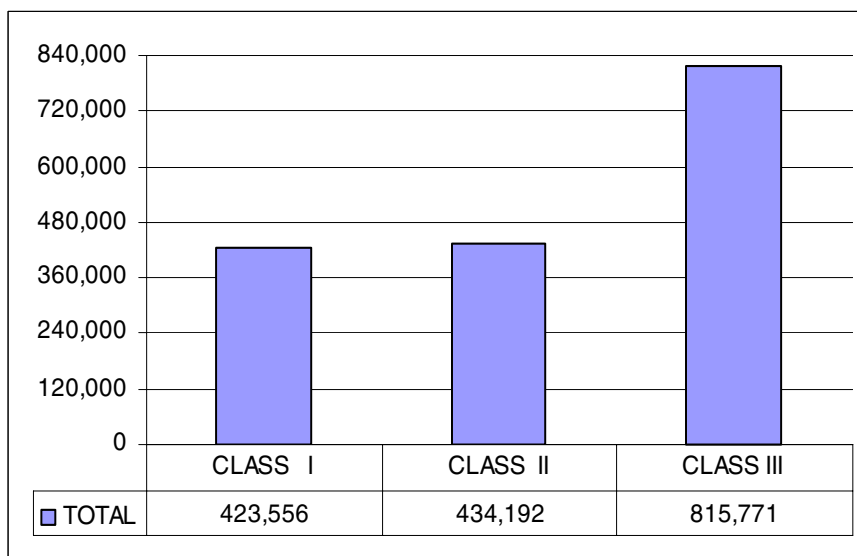


Figure 3: The frequency of the total active airman population during the study period 1994-96 is presented by class of medical certification.

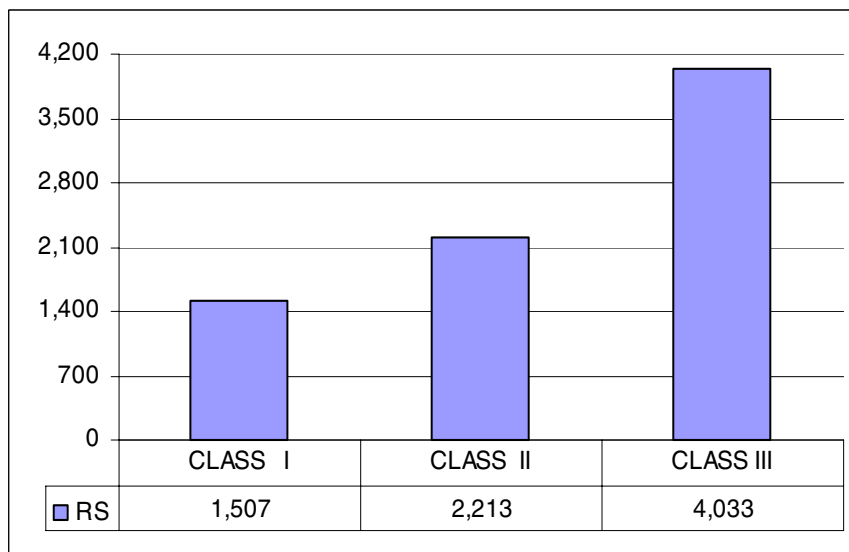


Figure 4: The frequency of the total active refractive surgery airman population during the study period 1994-96 is presented by class of medical certification.

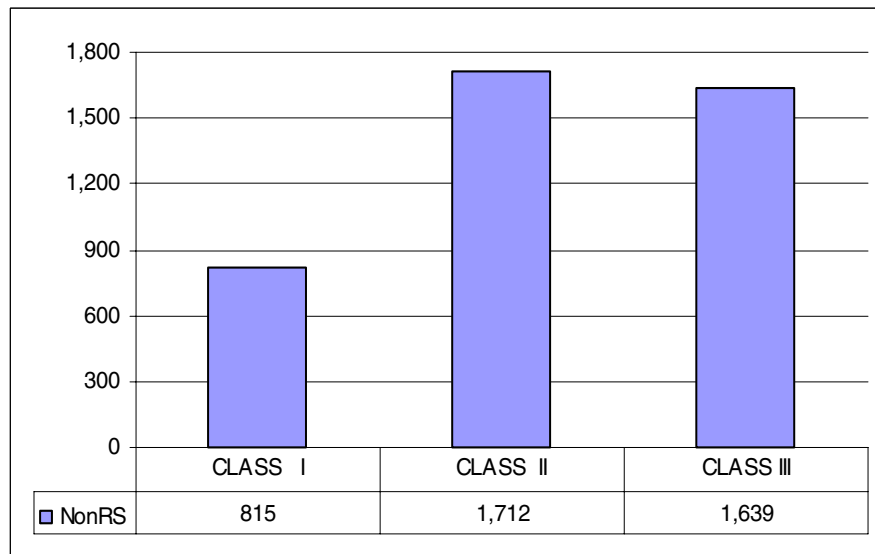


Figure 5: The frequency of accidents for the active non-refractive surgery airman population during the period 1994-96 are presented by class of medical certification.

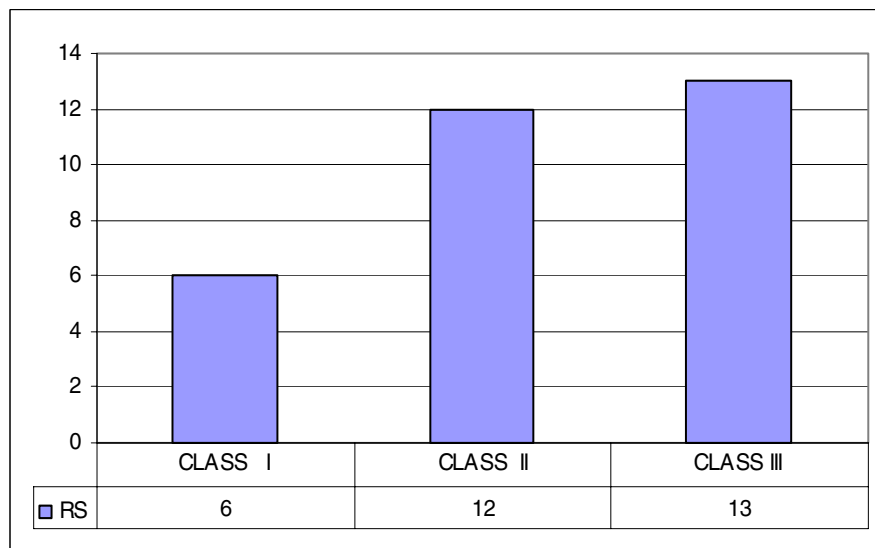


Figure 6: The frequency of accidents for the active refractive surgery airman population during the period 1994-96 are presented by class of medical certification.

ALL CLASSES						
<i>Groups</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>	<i>Variance</i>		
NonRS	18	47.092	2.616	3.580		
RS	18	69.494	3.861	19.427		
<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	13.940	1	13.940	1.212	0.279	4.130
Within Groups	391.116	34	11.503			
Total	405.056	35				
CLASS I						
<i>Groups</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>	<i>Variance</i>		
NonRS	6	2.429	0.405	0.019		
RS	6	5.296	0.883	0.936		
<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	0.685	1	0.685	1.434	0.259	4.965
Within Groups	4.775	10	0.478			
Total	5.460	11				
CLASS II						
<i>Groups</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>	<i>Variance</i>		
NonRS	6	16.274	2.712	0.249		
RS	6	20.470	3.412	10.426		
<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	1.467	1	1.467	0.275	0.612	4.965
Within Groups	53.377	10	5.338			
Total	54.844	11				
CLASS III						
<i>Groups</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>	<i>Variance</i>		
NonRS	6	28.388	4.731	0.656		
RS	6	43.728	7.288	29.708		
<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	19.609	1	19.609	1.292	0.282	4.965
Within Groups	151.822	10	15.182			
Total	171.431	11				

Table 1: Single-factor Analysis of Variance (ANOVA) was performed for aviation accidents occurring during the study period 1994-96. Non-refractive and refractive surgery accident rates were compared by class of medical certification and by total population. The differences between mean accident rates were found to be non-significant ($p > 0.05$) in all cases.

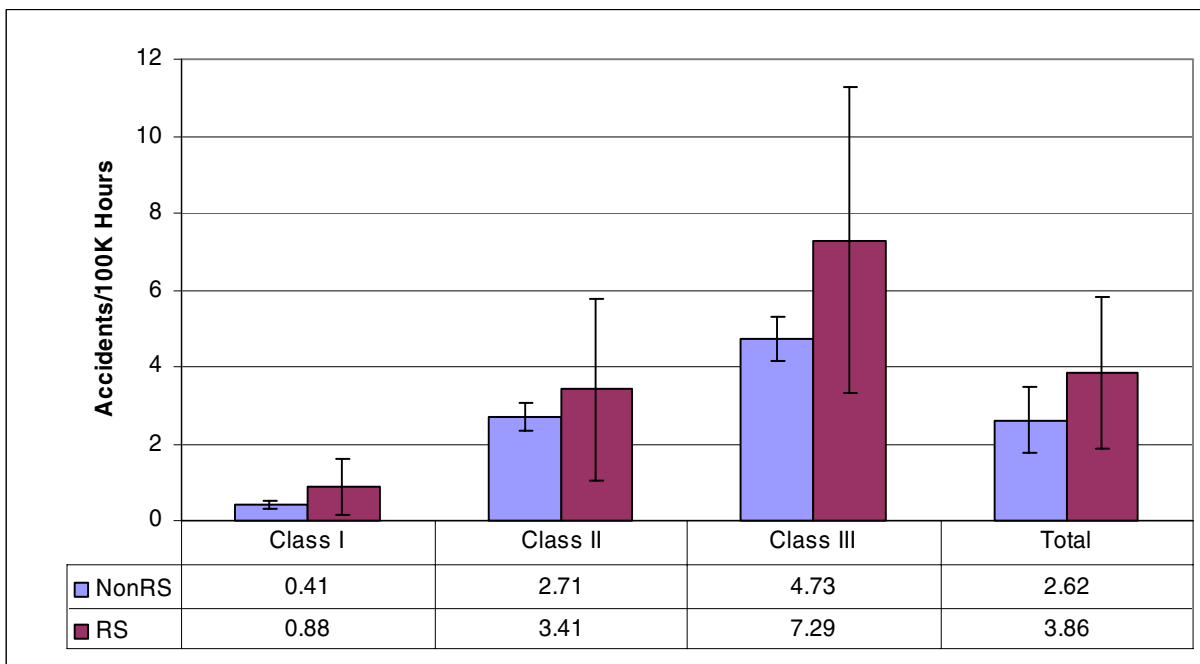


Figure 7: The non-refractive and refractive surgery accident rates per 100,000 hours of recent flight time for the period 1994-96, by class of medical certification, are presented. The vertical error bars indicate the 5 to 95% confidence interval.

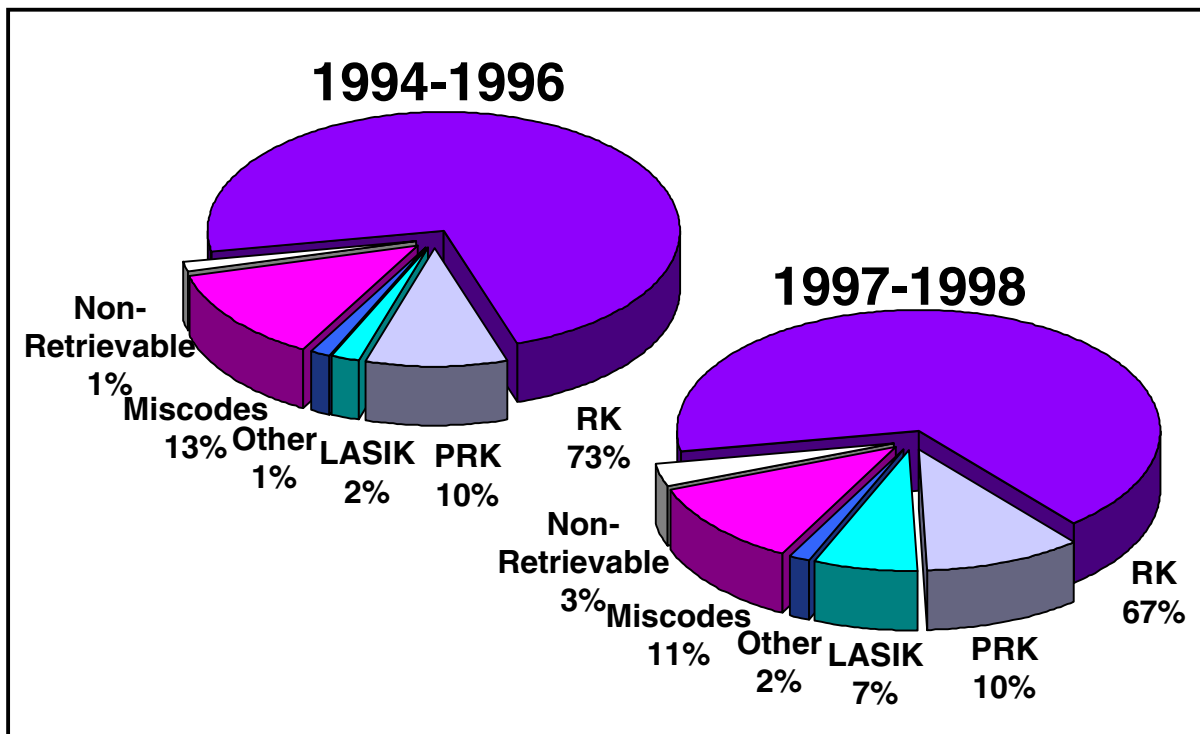


Figure 8: The two pie charts illustrate the percentage of refractive surgery in the civilian airman population by type of procedure for the periods 1994-96 and 1997-98.

between airmen with refractive surgery and aviation accidents. The higher accident rates for airmen with refractive surgery may be due to a number of contributing factors. These factors include irregularities in the data or data acquisition process, social-economic factors not shared by both groups, or a diminished physiological capability common to airmen with refractive surgery.

To investigate the possibility of factors that may have linked these accidents, the National Transportation Safety Board reports were reviewed for all 31 accidents involving airmen with refractive surgery. These reports revealed that approximately 90% of the accidents involved general aviation (Federal Aviation Regulations, Part 91). Environmental conditions that existed during these accidents included: 84% visual meteorological conditions, 71% daylight, 94% no precipitation, and 94% unrestricted visibility. Phases of flight included: taxiing (n=1), takeoff (n=5), cruise (n=8), approach (n=2), landing (n=8), emergency landing (n=1), maneuvering (n=5), and hovering (n=1). The information obtained from the accident reports was unremarkable, except that the majority of the accidents occurred during optimal visibility and weather conditions. The report narratives revealed only three references to visual difficulties. One report described the aircraft striking an unattended baggage cart while taxiing at night on a poorly-lit parking ramp. A second accident was a midair collision in which both pilots reportedly failed to “see-and-avoid” one another. (Note: The other pilot involved in this accident did not have refractive surgery.) The third accident occurred as the pilot attempted to land on a section of beach that he thought was wet sand, which was actually a 6 to 8-inch deep pool of water. The perceptual difficulties encountered during these three mishaps could not be directly associated to the pilots having refractive surgery with any certainty.

Based on its growing popularity in the general U.S. population (22,23,24), it is anticipated that an increasing number of laser refractive procedures will be performed on civil pilots. As mentioned previously, 1.3 million laser procedures were performed in the U.S. during the year 2000 (5), and there is an expected growth rate of 35-40% over the next five years (6). This trend has already been observed in the comparison of two data sets of refractive surgery in civil airmen for the periods 1994-96 and 1997-98 (see Figure 8). The total number of airmen with refractive surgery increased by approximately 37%, and there was a change in the distribution of the types of

refractive procedures. The percentage of RK decreased from 73 to 67%, PRK remained at 10%, while the percentage of LASIK procedures more than tripled from 2% to 7%.

RK is the most prevalent refractive procedure in the airman population during the study period. However, RK is being performed less frequently (25), and PRK has been substantially replaced by LASIK as the procedure of choice (26). Clinical studies conducted in the United States and other countries have provided valuable short-term information about laser refractive surgery. However, long-term stability (27,28) and possible variations in vision performance, due to normal age-related changes in the human visual system, will not be known for some time (29,30,31). If concerns regarding laser refractive procedures prove prophetic, it can have a severe impact on the visual performance of pilots and aviation safety in the future.

Although the vast majority of patients who have had laser refractive procedures experience satisfactory results, there is a small percentage of individuals who have less than optimal surgical outcomes (32,33). In some cases, enhancement procedures cannot improve the quality of vision that remains for these patients (34,35). The demands placed on a pilot's vision are often extraordinary. First-class airmen are tested every six months, and the vision standards for these aviators are stringent. A poor surgical outcome or complication perceived as a minor inconvenience to some individuals can be a career-compromising condition for the professional pilot. Before choosing refractive surgery, a pilot should be aware of the possible side effects associated with these procedures (36).

Subjective complaints following refractive surgery include reduced contrast sensitivity, increased glare sensitivity, and the loss of best-corrected visual acuity (10). Some patients, who report seeing well in normal room lighting conditions, have found night driving to be difficult or impossible due to aberrations (i.e., halos, starbursts, and ghost images) from street lights, traffic lights, and oncoming headlights (12). These complaints may be associated with residual corneal haze and/or de-centered ablation zones (37,38). Furthermore, under-correction of the refractive condition can result in poor distant vision, while over-correction can produce “premature” presbyopia (i.e., an inability to see objects at near distances clearly due to a loss of accommodation that normally occurs with aging) or exacerbate a pre-existing presbyopic condition (39).

Clinical studies have suggested that a number of factors can influence the results of laser refractive surgical procedures, including the magnitude of refractive correction, age, and gender. Several studies have concluded that the predictability of the resulting refractive correction decreases with increased refractive error (40,41,42). Other research suggests that, since they often experience less regression than younger patients who have similar procedures to correct equivalent refractive error, older patients have a higher frequency of over correction after refractive surgery (29,30). Some clinical studies suggest that women taking contraceptives (41), who become pregnant during the healing process (43), or who are treated with hormones for menopause have less predictable refractive results (44,45). Also, those exposed to high levels of ultraviolet radiation (solar radiation, tanning beds) were more prone to refractive regression and late-onset-corneal haze (41,46). Regression was significantly higher in those with ocular-surface disorders, such as dry eyes (41). One study found a significant myopic shift in the corneas of LASIK patients exposed to hypoxia when compared with myopic control subjects (47). These results could be particularly worrisome for pilots who are repeatedly exposed to high levels of solar radiation, the low-humidity environment of a cockpit, and altitude hypoxia.

In conclusion, airmen with refractive surgery are present in all classes of medical certification. Although mean accident rates for airmen with refractive surgery were higher in all classes of medical certificate holders, statistical analysis found that these rates were not significantly higher ($p > 0.05$) when compared with those for airmen without refractive surgery. Considering the anticipated increase in the number of laser refractive surgery procedures that will be performed in the future, the possibility of complications or side effects that may be compounded in the cockpit environment, and the lack of information concerning the possible long-term effects of newer procedures, further study is required. Additional research incorporating age stratification may help to determine whether the normal age-related changes in vision will influence the effectiveness of refractive surgical procedures as the pilot ages. Finally, since this study examined a refractive surgery population consisting primarily of pilots with RK, continued monitoring is necessary to determine if the newer laser refractive procedures perform satisfactorily in the aviation environment.

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¹ This report and all Office of Aerospace Medicine technical reports published between 1961 and the present are also available in full-text at the Civil Aerospace Medical Institute's Web site: http://www.cami.jccbi.gov/aam-400A/Abstracts/Tech_Rep.htm

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